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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2015-0814; FRL-9974-40]

Pesticides; Guidance for Pesticide Registrants on the Determination of Minor Use

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Agency is announcing the availability of a Pesticide Registration Notice (PR Notice) entitled, "Determination of Minor Use under Federal Insecticide, Fungicide, and Rodenticide Act Section 2(ll)." This PR Notice was signed by the Agency on March 7, 2018 and is identified as PR Notice 2018-1. PR Notices are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This PR Notice, which supersedes PR Notice 97-2, provides guidance to the registrant as to how EPA determines a "minor use." EPA seeks to identify and encourage the registration of pesticides for minor uses to protect communities from harmful pests. This PR Notice revises the method used by EPA for evaluating "sufficient economic incentive" under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This PR Notice explains how qualitative information may be used to inform the quantitative analysis and interpret the results, and clarifies that the United States Department of Agriculture's (USDA) most recent Census of Agriculture is the appropriate source for data on acreage in the U.S. to establish a minor use under the acreage definition in FIFRA 2(ll)(1).

FOR FURTHER INFORMATION CONTACT: Derek Berwald, Biological and

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who are responsible for the initial or continuing registration of pesticides. Entities that register pesticides with EPA's OPP typically fall under the NAICS Code 325300 – Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing. This action may also be of interest to persons using pesticides on sites that may be considered "minor" including persons engaged in crop and livestock production, and persons engaged in pest control in residential, commercial, and municipal areas including control of public health pests, and to the public in general. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How Can I Get Copies of this Document and Other Relevant Information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0814, is available either electronically though *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center, (EPA/DC) EPA West William Jefferson Clinton Bldg., Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The

telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

II. What Guidance Does this PR Notice Provide?

FIFRA defines a minor use of a pesticide as either a use on a crop grown on 300,000 acres or less in the United States or a use that lacks sufficient economic incentive to seek or maintain a registration but has private or social value. This PR Notice provides guidance to the registrant concerning the method used to determine if a use site is a "minor use" as defined by FIFRA 2(ll). In particular, the PR Notice describes the method for determining if the use "does not provide sufficient economic incentive." To date, EPA's interpretation of *economic* minor use in section 2(ll)(2) has been shaped by guidance provided in PR Notice 97-2. However, the approach outlined in PR Notice 97-2 does not consider critical factors that influence the incentives for registration.

EPA published and requested public comment on the draft Economic Minor Use PR Notice on June 6, 2016 (81 FR 38704). EPA received comments from seven entities. Most commenters were broadly supportive of the endeavor to improve upon PR Notice 97-2. Commenters supported the new process to qualify for minor use registration under FIFRA as more appropriate and simple by clarifying and updating economic definitions and treating registration of a pesticide as an investment. The Agency appreciates the comments provided by the public, and the Agency's responses to the comments for the draft PR Notice can be found at regulations.gov using docket ID number EPA-HQ-OPP-2015-0814.

This final PR Notice describes the revised approach to evaluate "sufficient economic incentive." It explicitly considers (1) the difference in time between incurring

costs of generating data for registration and obtaining revenue from product sales, (2) the multiple years over which revenue is generated, and (3) the costs of producing and distributing the product. The PR Notice provides suggestions about the data that can be used to conduct the analysis. Finally, the PR Notice explains how qualitative information may be used to inform the quantitative analysis and interpret the results. It also clarifies that the most recent USDA Census of Agriculture is the appropriate source for data on acreage in the U.S. to establish a minor use under the acreage definition in FIFRA section 2(ll)(1).

Registrants will typically seek to demonstrate that a site is a minor use in the context of requesting an extension of the exclusive use period for data submitted in support of a registration under FIFRA section 3(c)(1)(F)(ii) or a new exclusive use period for data submitted to support a registration under FIFRA section 3(c)(1)(F)(vi). These clauses are intended to provide incentives to registrants to obtain registrations for uses that might otherwise go unfulfilled because they offer low returns because of low demand.

The information collection activities associated with the activities described in this PR Notice are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*. The corresponding Information Collection Request (ICR) document for the Application for New and Amended Pesticide Registration has been assigned EPA ICR number 0277.16 and is approved under OMB control number 2070-0060.

III. Do PR Notices Contain Binding Requirements?

The PR Notice about the determination of a minor use is intended to provide

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guidance to EPA personnel and decision-makers and to pesticide registrants. While the

requirements in the statutes and Agency regulations are binding on EPA and the

applicants, this PR Notice is not binding on either EPA or pesticide registrants, and EPA

may depart from the guidance where circumstances warrant and without prior notice.

Likewise, pesticide registrants may assert that the guidance is not appropriate generally

or not applicable to a specific pesticide or situation.

Authority: 7 U.S.C. 136 et seq.

Dated: March 7, 2018

Richard P. Keigwin, Jr.

Director, Office of Pesticide Programs.

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